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nand U. Desai, Ph.D.	1653	
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## **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 10, 2005 has been entered.

# Withdrawal of Rejections

- 2. The rejection of claims 1, 5-11, 13-17, 20, 21, and 27-30 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph is withdrawn.
- 3. The rejection of claims 1, 5-11, 29, and 30 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, as failing to comply with the written description is withdrawn based on examiner's amendment to the claims.
- 4. The rejection of claims 1, 5-11, 13, 16, 17, 20, 21, and 27-30 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, enablement is withdrawn based on examiner's amendment to the claims.
- 5. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Studier et al. (Methods in Enzymology 185: 60-89 (1990)) is withdrawn based on examiner's amendment to the claims.
- 6. The rejection of claims 1 and 3 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sim, G-K. et al. (U.S. Patent 6,471,957 B1) in view of Lutz-Freyermuth, C. et al. (PNAS 87: 6393-6397 (1990)) is withdrawn based on examiner's amendment to the claims.

#### **EXAMINER'S AMENDMENT**

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Kirk Ekena on December 5, 2005.

The application has been amended as follows:

### Examiner's Amendment to the Claims:

- 1. (Currently Amended) A composition for targeting hepatocytes comprising: a T7 ligand covalently attached to a compound, wherein,
- a) said T7 ligand is selected from the group consisting of: T7 phage, modified T7 phage, T7 p17 protein, modified T7 p17 protein, T7 p17 derived peptide, T7 p17 rod domain, T7 p17 coiled coil domain, SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, and a peptide or synthetic peptide analog derived from SEQ ID 1, SEQ ID 14, SEQ ID 15, SEQ ID 16, SEQ ID 17, SEQ ID 18, SEQ ID 19, SEQ ID 20, SEQ ID 21, SEQ ID 22, SEQ ID 23, or SEQ ID 24; and[[,]]
- b) said compound is selected from the group consisting of: drug, component of a <u>drug or polynucleotide</u> complex and polynucleotide.
- 29. (Currently Amended) A pharmaceutical preparation comprising: a compound selected from the group consisting of: drug, component of a <u>drug or polynucleotide</u> complex, and

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polynucleotide covalently attached to a T7 ligand selected from the group consisting of: <del>T7</del> phage, modified T7 phage, T7 p17 protein, modified T7 p17 protein, T7 p17 rod domain, T7 p17 coiled coil domain, SEQ ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24.[[,]] and a peptide or synthetic peptide analog derived from SEQ ID 1, SEQ ID 14, SEQ ID 15, SEQ ID 16, SEQ ID 17, SEQ ID 18, SEQ ID 19, SEQ ID 20, SEQ ID 21, SEQ ID 22, SEQ ID 23, or SEQ ID 24.

- 30. (Currently Amended) A composition for targeting hepatocytes in vivo comprising: a T7 ligand covalently attached to a compound, wherein
- a) said T7 ligand is selected from the group consisting of: T7 phage, modified T7 phage;
  T7 p17 protein, modified T7 p17 protein, T7 p17 rod domain, T7 p17 coiled coil domain, SEQ
  ID NO: 1, SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18,
  SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID
  NO: 24, and a peptide or synthetic peptide analog derived from SEQ ID 1, SEQ ID 14, SEQ ID
  15, SEQ ID 16, SEQ ID 17, SEQ ID 18, SEQ ID 19, SEQ ID 20, SEQ ID 21, SEQ ID 22, SEQ
  ID 23, or SEQ ID 24; and [[,]]
- b) said compound is selected from the group consisting of: drug, component of a <u>drug or polynucleotide</u> complex and polynucleotide.
- 8. The following is an examiner's statement of reasons for allowance:

The prior art of record does not disclose the covalent conjugation of a compound with a T7 p17 tail fiber protein. The prior art of record shows the covalent conjugation of the first 11 amino acids of the gene 10 protein of T7 with a polypeptide sequence (cited in FINAL office

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action mailed 8/9/2005). Page 10 of the specification describes the enabled modified p17 proteins in Table 1a, which can be covalently conjugated to a complex that targets hepatocytes.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## Allowable Subject Matter

9. Claims 1, 3, 5-11, 13-17, 20, 21, and 27-30 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-91/97 (toll-free).

December 5, 2005

SUPERVISORY PATENT EXAMINER